

UNITED STATES PATENT APPLICATION

**TRAJECTORY GUIDE
WITH INSTRUMENT IMMOBILIZER**

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CROSS-REFERENCE TO RELATED APPLICATION

This patent application claims the benefit of priority, under 35 U.S.C.
Section 119(e), to U.S. Provisional Patent Application Serial Number
60/225,952, filed August 17, 2000, the disclosure of which is incorporated
10 herein by reference in its entirety.

FIELD OF THE INVENTION

This document relates generally to surgical trajectory guides. More
specifically, but not by way of limitation, it relates to apparatuses and methods
15 that facilitate alignment of surgical and observational instruments into a body.

BACKGROUND

In the treatment of some diseases or defects associated with a patient, it
has been found necessary to access specific targets within a patient. In the
20 treatment of some diseases of or defects of human beings, it has been found
necessary to access specific portions of the brain. Currently there are several
methods for inserting surgical and observational instruments into a patient's
brain.

U.S. Patent No. 3,055,370 issued to McKinney et al. shows one currently
25 used method for placing a surgical instrument to access a specific portion of the
brain. The surgical instrument of the '370 patent includes a ball which has a
bore. The direction of the bore can be changed. The instrument has an
elongated tube of a specific length. A stylet is inserted within the tube to access
the globus pallidus and perform a pallidotomy. An opening or burr hole is made
30 in the skull at a specific landmark on the skull. Next, X-rays are taken in the
fore-and-aft (AP) and lateral positions, and the line of the bar is projected
downwardly by a ruler both in the fore-and-aft (AP) and lateral positions, so that
the direction of the needle can be determined before it is inserted. When the
direction of the longitudinal axis of the tubular member is determined to be

satisfactory, a holder is threaded further into a tap to force a surface against a ball and lock a tubular member into place. Alignment of the trajectory is not measurable along a specific line occurring at the intersection of two planes. Alignment is dependent on placement of the burr hole at a specific location to
5 determine one plane. X-rays are used to determine another plane-based use of common landmarks on the skull. The end result is that an educated guess is being used to position the stylet at the globus pallidus for the pallidotomy. One shortcoming with the method of using X-ray imaging to direct a surgical or observational instrument, is that many of the destinations within a patient are not
10 viewable via X-ray. Another shortcoming relates to the slight shifting of intracranial contents, once a burr hole is placed and the dura and arachnoid are penetrated. Once cerebrospinal fluid is released via the burr hole, the intracranial contents (i.e. brain) may shift one or more millimeters. In such a case, the calculated trajectory is no longer accurate. Hence, there is an inherent
15 inaccuracy with the described scheme.

Several other methods are also used to place instruments, catheters, or observational tools into patients. Currently, surgical procedures are performed through craniotomy flaps or craniotomy burr holes. A burr hole of about 14 mm is made in the skull. Needles or probes are typically passed through the burr
20 hole into the brain using framed stereotaxy, frameless stereotaxy or freehand without stereotaxy.

The freehand method depends very heavily on the knowledge and judgment of the surgeon. In the freehand method, the surgeon determines the insertion point with a couple of measurements from a known landmark. The
25 surgeon then looks at the measured point, makes adjustments, determines the angle of insertion and then inserts the surgical instrument or tool.

In framed stereotaxy, a ring frame is mounted to the patient's skull by multiple (typically three or four) pins or screws. This ring frame is used to determine a three dimensional data set. From this data set, Cartesian coordinates
30 are calculated for both the lesion, the location of the pins or screws, and the fiducial marks on the frame. The ring frame fits into a large frame. A large frame is then attached to the patient in the operating suite. The large frame provides known positions and guides the surgical or observational instruments. The large frame is used to position the instrument to be introduced into the

patient through a burr hole so that it intersects the target. In frameless stereotaxy, the ring frame is replaced with several markings on the patient's skull which can be used to determine several known positions. The large frame is replaced by a camera. The camera is usually infrared or some such device.

5 Multiple sensors readable by the camera are placed on the instrument. For example, the surgical instrument or tool is provided with one or more light emitting diodes ("LEDs") which are tracked by the camera. The position of the surgical instrument can be calculated from the information from the LEDs on the surgical instrument or observational tool.

10 U.S. Patent No. 4,955,891 and U.S. Patent No. 4,805,615, both issued to Carol, each discuss the use of stereotaxy surgery with computerized tomographic ("CT") scanning. CT scanning is used to determine the exact position of a lesion or specific portion of the brain. After the exact position of the lesion or specific portion of the brain is determined, a phantom fixture is set up. The phantom
15 fixture replicates the position of the ring frame on the patient. A phantom target is set up. The instrument can then be positioned on the phantom such that it intersects the target. The information from the phantom can then be used in actually positioning the instrument in the operating suite.

U.S. Patent No. 4,998,938 issued to Ghajar et al. shows another surgical
20 device for facilitating the insertion of an instrument into a patient's cranial cavity through a burr hole. The device includes a guide having an end configured to pass into the burr hole. There is a separate locking member. A body member includes alignment markings to help with insertion of a catheter or stylet. Unlike the '370 patent, there is no movable member for adjusting the path of the guide.

25 The methods currently in use all have a number of shortcomings. Most of the techniques currently used to place a surgical instrument or observational tool within a patient employ a limited amount of accuracy. In particular, current framed, frameless, and freehand methods compute or predict trajectories on the basis of imaging data or anatomic landmarks that do not account for the slight,
30 but real shifting of the brain upon opening the cranium and meninges to the level of the subarachnoid space. This inherent inaccuracy inherently limits the success of these various methodologies. In other words, these systems do not use any means of updating the data files to include data obtained following the placement of a surgical burr hole and opening of the meninges. In addition, all

the methods require large amounts of judgment on the part of the surgeon placing the surgical instrument or tool, and in particular, offer no direct feedback on the success or failure of the trajectory to reach the target. Very few of the techniques use an imaging or scanning apparatus to aid in the placement of the surgical instrument or observational tool. The only one that does requires a phantom frame and target to be set up to simulate the real geometry. In short, none of the apparatuses appear to use an imaging or scanning apparatus as extensively as they could be used to minimize the time and effort needed to accurately place a surgical instrument into a patient, and to offer immediate data on the success or failure of the trajectory to reach the target.

The trajectory guide system taught in Published International Patent Application PCT/US98/10008 (International Publication number WO 98/51229) addresses these and other shortcomings of prior art surgical working platform systems as described above. The disclosed system provides a means for accurately determining the trajectory of a surgical instrument within a passage which in turn lies within a guide or positioning stem that extends from a movable member that is selectably lockable in position with respect to a base. Some embodiments of this system employ removable guide stems or positioning stems that can be removed from the movable member once an appropriate trajectory has been chosen and a surgical instrument inserted into the passage formed within the chosen stem and movable member. One disadvantage of this system is that there may be axial movement introduced to the instrument by the process of removing the stem; that is, the instrument may be disadvantageously introduced further into the body, or disadvantageously removed farther from the body, by the axial motion of the stem as it is removed.

SUMMARY

This document discusses a method and apparatus for accurately aligning the trajectory of, guiding of, and introducing or withdrawing a surgical instrument. The apparatus includes a base which has a movable member positioned in or movably attached to the base. The movable member has a passage therein which forms a portion of the trajectory path. The movable member also includes a removably attachable guide stem which has an opening therein. The guide stem is attached to said movable member such that the

opening in the guide stem substantially aligns with the passage in the movable member. A removable positioning stem can be placed within the removably attached guide stem for purposes of trajectory alignment. In one embodiment, the removable positioning stem includes an MRI alignment stem or image-guided workstation probe with LEDs or light reflectors.

A positioning stem further includes a first locator and a second locator. The first and second locators are associated with two different portions of the positioning stem so that they are essentially two points on a line. The first and second locators are also locatable by a scanning or imaging system. The positioning stem is inserted into the guide stem and used to position the movable member. Moving the positioning stem while within the guide stem moves the passage therein to different trajectories. Once the passage within the movable member is more or less aligned with a target within the body, a locking member locks the movable member into a fixed position.

The base, movable member and guide stem are adapted for clinical applications in which a distal portion of an instrument is positioned in a specified targeted tissue location, and further in which a proximal portion of the instrument is implanted or tunneled under a skin flap. In these applications, it is desirable to keep the base of the apparatus securely attached to the patient's body (typically attached to the patient's skull), and bend or otherwise angle the flexible instrument over the edge of the base until it is extended generally parallel to the body surface, between the body and overlying skin flap (or in the case of attachment to the skull, the scalp flap). To provide sufficient resistance to potential infection by microorganisms which may migrate down the shaft of the instrument, a tunnel of approximately 4-5 centimeters in length is preferred, but the exact length will depend on the specific clinical situation.

In one embodiment the first locator and the second locator are readable by a magnetic resonance imaging apparatus. The locator can include a fluid readable by a magnetic resonance imaging apparatus or a source of radio frequency, such as a coil, which is readable by a magnetic resonance imaging apparatus. In the latter embodiment, the first and second locators may be small radio frequency (RF) coils that detect an electromagnetic signal in a magnetic resonance imaging environment. The electromagnetic signal detected can be used to locate the first and second locators. The line formed by the first locator

and the second locator may be substantially aligned with the centerline of the passage in the movable member or may be offset from the centerline of passage in the movable member. In other embodiments, the first and second locators may be light emitting diodes which are readable by an infrared camera.

5 The first and second locators may be located within an essentially solid plastic positioning stem, or in another embodiment, the first and second locators may be located within an MR-visible chamber within the positioning stem. In the latter embodiment, the chamber may be filled with an MR-visible fluid (paramagnetic, for example), which can be used to afford a first approximation
10 of alignment. The first and second locators may be either MR-visible (different than the MR-visible chamber) or may be MR-invisible, in which case they would exhibit a negative image against the background of the MR-visible fluid within the larger chamber of the positioning stem. Advantageously, the fluid in the chamber produces an image which can be easily located and can be used to
15 roughly align the positioning stem. The MR-visible or MR-invisible fluid of the first and second locators can then be used for fine or precise alignment.

 The movable member includes a threaded axial opening which receives and engages a threaded end of the guide stem. The movable member may be a ball capable of swiveling with respect to the base.

20 The movable member may also include a separate relaxable stabilizer or, alternatively, a portion of the movable member is manufactured to provide similar characteristics. In either case, the relaxable material of the instrument stabilizer holds a catheter or other instrument in place so that a guide stem may be unthreaded or otherwise detached from the movable member and removed
25 axially, over the body of the catheter or instrument, without the catheter or instrument being subjected to undesirable axial motion. Alternatively, a rigid material may be used, and a passage through the rigid material is at least partially offset with respect to the trajectory passage through the movable member to reduce an effective area of the passages and grasp an instrument.

30 In another embodiment, the movable member may also include a stage which allows for planar movement in a direction intersecting the trajectory. A surgical instrument, such as a needle, probe (cryotherapy probe, laser probe, RF ablation probe, microwave interstitial therapy probe, or focused ultrasound therapy probe), catheter, endoscope, or electrode, can then be inserted through

catheter into the groove in the base plate; tunneling the proximal portion of the catheter under the skin to a desired location; securing a cap to the base plate (over the moveable member and catheter); and laying the skin flap over the base plate and suturing it in place. For a two-piece base including a mounting seat
5 and a locking collar, after the guide stem and locking member are removed, the locking collar is also removed to leave behind the lower profile mounting seat portion of the base. Other aspects of the present apparatuses and methods will become apparent upon reading the following detailed description of the invention and viewing the drawings that form a part thereof.

10

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which are not necessarily drawn to scale, like reference numerals describe substantially similar components throughout the several views. Like reference numerals having different letter suffixes represent
15 different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

Figure 1 is a block diagram of a patient scanning system.

Figure 2 is a side view of a patient on which the trajectory guide is being
20 used.

Figure 3 is an exploded isometric view of the trajectory guide with a removably attached guide member installed.

Figure 4 is an exploded isometric schematic view of the trajectory guide with a removably attached positioning member installed inside the removably
25 attached guide member.

Figure 5a is an exploded isometric view of the movable member or ball and guide stem of the trajectory guide.

Figure 5b is a cross-sectional view of the movable member or ball of the trajectory guide.

Figure 5c is a cross-sectional view of the movable member or ball of the trajectory guide after insertion of the relaxable stabilizer and removably attached
30 guide member.

Figure 5d is a cross-sectional view of the assembly of Figure 5c, after further insertion of a catheter or instrument.

Figure 5e is a view of the assembly of Figure 5d, after unscrewing and partial removal of the removably attached guide member.

Figure 5f is a view of the assembly of Figure 5e, after complete removal of the removably attached guide member.

5 Figure 5g is a close up side view of a portion of Figure 5f.

Figures 6a and 6b are isometric views of one example of a base of the trajectory guide.

Figures 6c-6e are bottom, side, and top views, respectively, of the base of Figures 6a and 6b.

10 Figure 6f is a cross sectional view taken along the line 6f-6f of Figure 6c.

Figure 6g is a side view of the base of Figure 6c.

Figures 7a and 7b are isometric views of one example of the locking member of the trajectory guide.

15 Figure 7c is a top view of the example of the locking member of the trajectory guide.

Figure 7d is a cross-sectional view of the example of the locking member of the trajectory guide, taken along the line 7d-7d of Figure 7c.

Figures 8a, 8b and 8c are perspective views showing the use of a base with a flexible instrument that is tunneled under a skin flap.

20 Figure 9a is a perspective view of one example of a cap member of a trajectory guide.

Figures 9b and 9c are side and bottom views, respectively, of the cap member of Figure 9a.

Figure 9d is a close up side view of a portion of Figure 9b.

25 Figure 10a is an isometric view of a preferred embodiment of a alignment or positioning member for the trajectory guide.

Figure 10b is an exploded side view of the embodiment of Figure 10a.

Figure 10c is a side view of a portion of the embodiment of Figure 10b.

30 Figure 10d is a side cross sectional view of the embodiment of Figure 10c.

Figure 10e is an end view of the embodiment of Figure 10d.

Figure 10f is a detailed view of a portion of the embodiment of Figure 10e.

Figure 11a is a partial cutaway side view of an alternative embodiment of the base and alignment guide.

Figure 11b is a side view illustrating the use of the alternative embodiment of Figure 11a with the alignment member from Figure 10.

5 Figure 12a is a partial cutaway isometric view of yet another alternative embodiment of the base and alignment guide.

Figure 12b is an isometric view illustrating the use of the alternative embodiment of Figure 12a.

10 Figure 13a is a top perspective view of a movable member, a guide stem, and a two-piece base including a mounting seat and a collar.

Figure 13b is a top exploded view of a cap and the mounting seat and the movable member of Figure 13a.

Figure 13c is a bottom exploded view of the mounting seat and cap of Figure 13b.

15 Figure 13d is a bottom perspective view of the mounting seat and cap of Figure 13b.

Figure 13e is a top perspective view of the cap and mounting seat of Figure 13b.

20 Figure 14a is a top perspective view of a two-piece base, including a mounting seat and collar, and a movable member.

Figure 14b is an exploded side view of the two-piece base of Figure 14a.

Figure 15a is a top perspective view of a low-profile mounting seat, movable member and guide stem.

Figure 15b is a side view of the apparatus illustrated in Figure 15a.

25 Figure 16a is a top view of a low-profile mounting seat, movable member, and collar.

Figure 16b is a side view of the mounting seat and collar of Figure 16a.

Figure 16c is a top exploded view of the two-piece base provided by the mounting seat and collar of Figures 16a and 16b.

30 Figure 17 is a top perspective view illustrating an example of an instrument that has been laterally bent into one of the grooves of the mounting seat of Figures 16a-16c.

Figure 18a is a bottom perspective view of an example of a low-profile mounting seat and cap.

Figure 18b is a top view of the cap and mounting seat of Figure 18a.

Figure 18c is a side perspective view of the cap and mounting seat of Figures 18a and 18b.

Figure 19a is a side view of a mounting seat, ball, and stabilizing cap.

5 Figure 19b is a top view of the ball and cap with aligned openings.

Figure 19c is a top view of the ball and cap with offset openings to grasp and stabilize an instrument.

DETAILED DESCRIPTION

10 In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the
15 embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents. In
20 this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one. Furthermore, all publications, patents, and patent documents referred to in this document are incorporated by reference herein in their entirety, as though individually incorporated by reference. In the event of inconsistent usages between this documents and those
25 documents so incorporated by reference, the usage in the incorporated reference(s) should be considered supplementary to that of this document; for irreconcilable inconsistencies, the usage in this document controls.

This application incorporates International Patent Application PCT/US98/10008 (International Publication number WO 98/51229) by
30 reference, together with the disclosure of its U.S. counterpart, issued U.S. Patent No. 5,993,463, which is also incorporated herein by reference in its entirety.

35

Scanning System Example

Figure 1 is a block diagram of a patient scanning system 100. The specific scanning system shown is for a magnetic resonance imaging ("MRI") system. An MRI scanning system 100 includes a computer 102. The computer 102 includes a central processing unit ("CPU") 104 and memory 106. The CPU 104 and memory 106 has the capacity to perform multiple calculations used to determine images as well as positions of various organs, or portions or within an image field. The computer 102 controls an image data processing portion 110, a system controller and waveform generator portion 120, and an XYZ gradient producing portion 130. The XYZ gradients are amplified and used to provide a gradient magnetic field in the X, Y, and Z directions as part of a magnet system 140. The magnet system 140 includes a magnet which produces a magnetic field through which a patient can pass. The shape of the magnet varies among MRI systems. The shape of the magnet and its relation to the table upon which the patient lies, determines whether the patient can be accessed by a surgeon while an MRI is being performed. There are many styles of MRI devices that do not place the surgeon within a close enough proximity to allow access to the patient during an MRI scan operation.

The MRI system 100 also includes gradient amplifier 150. Also included are a set of RF amplifiers 160 and RF coils 162 which are used in conjunction with the magnet system 140 to produce and transmit RF pulses in the magnetic field. Either the same RF coil or another RF coil is used to detect the MR signals from the interrogated tissues. This detected MR signal is then amplified by a preamplifier 164 and received by a receiver 166 for transmission to the data acquisition system 170 and then transmitted to the image data processing computer system 110. The data acquisition system is input to the system controllers and waveform generator portion 120 of the computer 102 as part of a feedback loop. The data is interpreted and placed on a display 180 associated with the computer of the MRI system 100. The computer 102 and the CPU 104 and memory 106 can use data acquired from the MRI system 100 to build up images of a portion of the patient which is being scanned. The images are typically referred to as slices. For example, a horizontal slice and a vertical slice can be made of the portion of the body or patient being imaged. The computer can also recalculate and build other slices for use by doctors and radiologists

having any selected orientation needed to facilitate study of various items within a patient. For example, lesions can be found within the body as well as certain organs. Different slices can be requested to facilitate study of these targets. From the data acquired, the position of the lesions or organs can also be very accurately determined using a Cartesian or polar coordinate system. The above description of the MR scanner is simply for demonstrative purposes and multiple alternative MR scanning systems can be described herein.

Trajectory Guide Example

Within some parts of a patient, it is critical to very accurately place a surgical instrument. For example, in neurosurgery, it is very critical to have instruments, such as catheters or needles, placed very accurately within the cranium or head of a patient. Figure 2 shows a side view of a patient on which trajectory guide 200 is being used. The trajectory guide 200 includes a base unit 210, a movable member 220, a locking member 230 and a guide stem 240. The base unit 210 is attached to the skull of the patient. In the particular embodiment shown, the attachment is made by way of bone screws. However, it is contemplated, that there may be any number of ways to attach the base 210 to the skull. For example, the base 210 could also be threaded to screw into a burr hole 250. The flange could also be added to the base 210 to attach the base to the skull.

The movable member 220 has an axial opening 222 which is shown in Figure 2 as dotted lines. The guide stem 240 also has an elongated opening 242 therein. The opening 242 is also shown as dotted lines in Figure 2. The passage 242 in the guide stem 240 and the axial opening 222 in the movable member or ball 220 form a line or a trajectory 260 which intersects with a target 270 within the patient. The guide stem 240 and movable member or ball 220 form the first part of the trajectory 260. A surgical instrument or observational tool can be inserted into the opening 242 of the guide stem 240 and passed through the passage in the movable member 220 and then further inserted into the patient a selected distance to the target 270. The opening 242 in the guide stem 240 and the passage 222 in the movable member 220 guide a surgical instrument along the trajectory 260 to the target 270. Of course, the movable member 220 is

locked into place by locking member 230 before a surgical instrument 280 is placed through the opening 242 in the guide member 240.

Figure 3 shows an exploded isometric view of the trajectory guide 200 with a guide member installed. As shown in Figure 3, the trajectory guide 200 is comprised of a base 210, a movable member 220, a locking member 230, and a guide member 240. The base 210 includes a cylindrical portion 212 and a flange 214. The flange 214 includes a plurality of countersunk screw openings 215, 216, and 217. The countersunk screw openings 215, 216, and 217 receive bone screws which are screwed into the skull bone or the bone of a patient. The cylindrical portion 212 fits within the burr hole 250 in the patient. The base also includes a semi-spherical seat 218. Although not shown in Figure 3, there is an opening in the base 210 having a first end which terminates at the seat 218 and another end which terminates at the bottom of the base 210.

As shown in Figure 3, the movable member 220 is essentially a spherical member or a ball. The spherical member or ball fits within the seat 218. The spherical member or ball moves freely within the seat 218. The ball-shaped movable member 220 also has an opening. The opening passes through the ball shaped movable member. One end of the opening may have a set of internal threads therein, which can be used to receive mating threads which are placed onto the guide stem or member 240 or positioning stem (discussed with respect to Figure 4).

The locking member 230 also has an opening therethrough. The locking member 230 includes a cylindrical bottom portion 232 and a flange 234. The opening through the locking member 230 has sufficient space to allow movement of movable member 220 when the locking member is in an unlocked or untightened position. Although not shown in Figures 3 or 4, the bottom of the cylindrical portion 232 of the locking member 230 includes a set of external threads. The set of external threads engage a set of internal threads on the base unit 210 (shown in Figures 6a-6g). As will be detailed later, when the external threads of the locking member 230 are engaged with the threads on the base 210, a portion of the locking member engages the movable member 220 to fix the movable member and the axial opening 222 therethrough at a fixed position.

A guide stem or guide member 240 is also shown in Figure 3. The guide stem has an elongated opening 242 therein. The elongated opening passes

through the length of the guide stem 240. One end of the guide stem includes a set of external threads which engage the internal threads of the spherical, movable member 220. When the external threads of the guide stem 240 engage the internal threads of the movable member 220, the opening 242 is substantially aligned with the axial opening 222 in the movable member. The opening 242 and axial opening 222 form the first part or guide for the trajectory 260 to the target 270 within the patient. It should be noted that the movable member 220 need not necessarily be a spherical element, although the spherical shape allows the ball to have a universal joint type swivel action which is preferred. It should also be noted that the locking member 230 can be formed in most any shape. A flange 234 is useful in that it allows additional leverage for tightening or loosening the locking member. Any shape capable of being turned or placed into a locking position with respect to the movable member 220 is acceptable.

15 **Positioning Member Example**

Figure 4 is a schematic illustration that shows an exploded isometric schematic view of the trajectory guide 200 with a positioning member 400. Figure 4 is a schematic illustration intended to illustrate the functionality of the positioning member. In Figure 4, an end 410 of positioning stem 400 has been inserted into guide stem or guide member 240. Positioning stem 400 may also include a first locator 420 and second locator 430. First locator 420 includes a small opening 422 located at one end of the positioning stem 400. The small opening 422, which is shown in phantom in Figure 4, is filled with a fluid or a substance that can be seen by a scanning device such as the MRI scanning device 100 described and shown in Figure 1. After a fluid or substance is inserted into the opening 422 the end is sealed with a cap and adhesive. Similarly, the second locator 430 includes an opening 432 which contains a substance which is readable by a scanner such as an MRI scanner shown in Figure 1. As shown in Figure 4, the first locator 420 and the second locator 430 are coaxial with the axis of the cylinder formed by the positioning stem 400. It is contemplated that a first locator 420 and a second locator 430 could also be formed in an offset position from the axis of the cylinder formed by the positioning stem 400.

Figures 10a-10f show one example of a positioning stem. In Figure 10b, positioning stem 1700 includes a main portion 1710 having a substantially hollow portion 1711 capable of accepting optional end cap 1712. This two-piece construction may be used, for manufacturing reasons, but is not required if a one-piece construction performing the same functionality is desired. A fluid such as (but not necessarily) saline, which is readable by nuclear magnetic resonance (NMR) imaging system, is housed or kept in a chamber 1711 of positioning stem 1700. In this example, the fluid is contained between a proximal portion 1750 of end cap 1712 and a distal portion 1760 of main portion 1710. The fluid within chamber 1711 can be easily located under NMR and is used for alignment of the positioning stem, so that opening 222 within movable member 220 is on a straight line trajectory with a target within the patient.

Alternatively, positioning stem 1700 may include a region of solid material that appears on the MR image only by virtue of its absence of MR visibility.

A series of bump-like protrusions or other features 1740 are arranged around a circumference of a distal portion of tapered distal shaft end 1730. Similarly, a series of box-like features 1770 are arranged around the central portion of the main portion 1710, proximal of the tapered distal shaft end 1730 and distal of a stop 1780. Features 1740 and 1770 are optional features that help hold positioning stem 1700 in place as it is inserted into guide stem 240 until it is stopped in place by stop 1780.

Movable Member Example

Figures 5a and 5b show one example of a movable member 220 that includes two mating, substantially hemispherical portions 220a and 220b that, when assembled, provide a substantially spherically shaped movable member 220. Movable member 220 has an axial opening 222 therein. Axial opening 222 includes a first opening 223 in upper hemispherical portion 220a, and a second opening 224 in lower hemispherical portion 220b. The inside surface of first opening 223 is threaded as indicated by reference numeral 225. First opening 223 and threads 225 receive an external threaded portion 241 of guide stem 240. Second opening 224 is of a sufficient diameter to allow an instrument, such as a needle, probe, catheter, endoscope, or electrode to pass through the axial opening

222. Movable member 220 is made of a rigid or semi-rigid biocompatible polymer material. Suitable materials include polycarbonate or DELRIN®.

Lower hemispherical portion 220b further includes a recess 226 sized and shaped to accept a relaxable stabilizer 227. Relaxable stabilizer 227 is sized
5 and shaped to complement the size and shape of recess 226, thus fitting closely inside recess 226 so as not to move out of proper position inadvertently. Also, relaxable stabilizer 227 has an axial opening 228 that generally is coaxial with axial opening 222 of the movable member 220.

Because movable member 220 is preferably a relatively stiff material
10 such as polycarbonate, and relaxable stabilizer 227 is relaxable and therefore made of a relatively more compliant material such as silicone, the two hemispherical portions 220a and 220b and the relaxable stabilizer 227 will generally be manufactured separately and assembled into the configuration shown in Figure 5b. However, the scope of the invention includes an integrally
15 constructed movable member having a material that is relaxable, and that otherwise performs the functions of the relaxable stabilizer as described below. Other suitable materials for relaxable stabilizer 227 include latex, C-flex, Viton, Buna-N, polyurethane, Kraton, and Santoprene.

Figures 5c through 5g illustrate one process of positioning a instrument
20 229 within the movable member 220 so as to restrict or prohibit axial motion of the instrument 229.

Before attachment of guide stem 240 to movable member 220 as shown in Figure 5c, a suitable tool (not shown) is used to stretch (or otherwise increase the inside diameter of) the relaxable stabilizer 227, until the axial opening 228 of
25 relaxable stabilizer 227 is large enough to accept the outer diameter of the guide stem 240. This permits the stem to be fully inserted into the movable member 220, through the stretched axial opening 228 in relaxable stabilizer 227, and then screwed into place utilizing external threads 241 and internal threads 225. The result of this operation is shown in Figure 5c.

30 Relaxable stabilizer 227 is sized and shaped such that: (1) upon removal of the tool, the previously stretched inside diameter of its axial opening 228 will attempt to return to a size somewhat less than the outer diameter of guide stem 240; but (2) relaxable stabilizer 227 will not hold guide stem 240 so tightly that it cannot be removed by unscrewing it from the movable member 220.

Before removal of guide stem 240, an instrument 229 may be inserted into the passage through opening 242 of guide stem 240, as shown in Figure 5d. Then, as guide stem 240 is removed from the vicinity of relaxable stabilizer 227 as shown in Figure 5e, relaxable stabilizer 227 will continue to return to a size that applies sufficient pressure or friction to the outer diameter of the instrument 229. This prevents axial migration of instrument 229, both while removing the guide stem 240 entirely over the proximal end of instrument 229, and also during any subsequent movement of the proximal segment of the instrument 229 as instrument 229 is secured or tunneled as described herein. Figures 5f and 5g are closeup views of relaxable stabilizer 227 after it is relaxed back into a position that will securely hold instrument 229 in place.

From this description it can be appreciated that the relaxable stabilizer 227 operates in a manner exactly opposite from known stabilization techniques, because the relaxable stabilizer 227 relies on self-relaxation to provide stabilizing force to instrument 229, as opposed to techniques in which compression of a material provides stabilization. For example, the well-known Touhy-Borst valve uses a compressible "O-ring" to provide stabilization of objects such as guidewires, leads, catheters, and the like upon twisting by a clinician's hand, but the present relaxable stabilizer stabilizes instruments by relying on relaxation, not compression.

Base Example

Figures 6a to 6g show an example of base 210 of trajectory guide 200. Base 210 includes a generally cylindrical portion 212 and a flange 214. Flange 214 includes openings 215, 216, and 217. Flange 214 also a seat 218 that receives movable member 220. Seat 218 is part of an opening 600 which includes an internally threaded portion 610. Internally threaded portion 610 is dimensioned so as to receive the threads of cylindrical portion 232 of locking member 230. Groove 219 lies in base 210 and is sized and shaped to accommodate a flexible instrument 229 or other instrument, as discussed further herein with respect to a stabilization or tunneling procedure.

In other embodiments, base 210 may separated into two or more pieces. Figures 13a-13e, 14a-14b, 15a-15b, 16a-16c, 17, and 18a-18c show several examples of structures and methods of using a multi-piece base 210, such as a

separate seat/mount and an internally threaded locking collar attachable thereto
The internal threads of the locking collar receive the external threads of the
cylindrical portion 232 of locking member 230. By separating base 210 into
more than one piece, its profile above the skull may advantageously be reduced.

5

Lockable Member Example

Figures 7a-7d illustrate an example locking member 230 of trajectory
guide 200. Locking member 230 includes cylindrical portion 232 and flange
234. The external surface of the cylindrical portion 232 is threaded to form a
10 threaded external surface 700. The threads associated with the externally
threaded surface 700 are dimensioned so as to engage the internally threaded
surface 610 of opening 600 of base 210. Locking member 230 also includes an
opening 710 which passes through locking member 230. Locking member 230
also has a locking surface 720. In this particular example, locking surface 720 is
15 shaped so that it smoothly engages the spherical face of movable member 220.
Flanges 234 are outwardly extended so that the threads of the threaded surface
700 can be easily engaged with internal threads 610 of opening 600 of base 210.
Other geometric shapes could be used for the locking member and other locking
surfaces could be employed.

20

Instrument Placement Example

In operation, a patient undergoes a scan with an apparatus such as an
MRI or magnetic resonance imaging system 100 as part of a normal diagnostic
medical procedure. A scan can be used to locate a particular organ within a
25 patient or to locate lesions or any other target 270 within the patient. It should
be noted that targets are not necessarily limited to being within the head of a
patient. There can also be other areas of a patient where it would be critical to
accurately place a surgical or observational tool. In addition, it should also be
noted that the patient need not necessarily be human. A patient may include any
30 living animal. Once a target is found and located using an MRI or other
scanning system, base 210 of trajectory guide 200 can be attached to the patient.
The base is affixed to the patient in an area near the target 270. The computer
102 of scanning device 100 is used to determine the exact location of the target
270. The exact location can be found in any type of coordinate system, although

normally a Cartesian coordinate system is used. Once base 210 is attached to the patient, the remaining portions of trajectory guide 200 are attached to base 210. In other words, movable member 220, guide stem 240, locking member 230, and positioning stem 400 are added to form a complete trajectory guide 200.

5 Scanning system 100 reads first locator 420 and second locator 430 of positioning stem 400. A line defined by first locator 420 and second locator 430 is calculated by computer 102. The calculated line corresponds to the center line of axial opening 222 and opening 242 of guide stem 240. If the line aligns with target 270, locking member 230 is used to lock movable member 220 into
10 position. If the line does not intersect target 270, positioning stem 400 is moved until the line formed by first locator 420 and second locator 430 intersects target 270. If the patient and positioning stem 400 can be easily reached by a surgeon during a scanning operation, positioning stem 400 can be moved or readjusted manually. If the patient is remote from the surgeon or cannot be reached by the
15 surgeon, a hydraulic or other actuator may be used to move positioning stem 400. Once such a trajectory line is formed, the locking member 230 is secured.

 After fixing the position of movable member 220, positioning stem 400 is removed from guide stem 240. Opening 242 in guide stem 240, and opening 224 in movable member 220 form the trajectory 260. An instrument 229 may be
20 placed through the guide opening to intersect target 270.

Tunneling Procedure Example

 Figures 8a, 8b and 8c illustrate one procedure for securing the distal portion of a flexible instrument 229 so that the proximal portion of flexible
25 instrument 229 may be tunneled under a skin flap. Figure 8a shows base 210 positioned against a surface 304 of a body, *e.g.*, a skull of a patient.

 Base 210 is attached to the patient as described above. Flexible instrument 229 extends through movable member 220 to target location 270 and is secured in place by relaxable stabilizer 227 (not shown in Figures 8a-8c),
30 again as described above. As shown, guide stem 240 has been removed over the proximal (as shown, the upper) portion of flexible instrument 229. In this example, base 210 is a multi-piece base in which the locking collar has also been removed.

In Figure 8b, the proximal portion of flexible instrument 229 has been laterally bent into groove 219 (shown in Figure 8a and covered by the instrument 229 in Figure 8b) so that it lies generally parallel to the surface 304 of the body and extends for approximately 5 cm. As noted before, this distance is a typical example, but depends on the clinical situation. The proximal end of instrument 229 is then turned generally upward, away from the surface 304 of the body, for a distance of approximately 2 cm (again, a typical example but dependent upon clinical conditions). A rigid or flexible cap 310 has been inserted into the opening 218 of the base 210. In one example, outer ridges of cap 310 engage internal threads 610 of base 210 to hold cap 310 in place. In another example, snap feet on cap 310 engage mating features of base 210 to hold cap 310 in place. This covers the portion of moveable member 220 remaining in base 210.

In Figure 8c, skin flap 221 (which would be a scalp flap in neurosurgery) is placed over the surface 304 of the body to cover base 210, cap 310, and the proximal portion of instrument 229. A suitable hole in the skin flap permits the upturned proximal portion of instrument 229 to be exposed outside the skin flap.

Cap Example

Figures 9a-9d illustrate one example of cap 310 in detail. In this example, cap 310 includes a relatively larger top 320 and a relatively smaller, generally cylindrical base 330. The exterior of base 330 also has an opening 340 designed to permit the flexible catheter to bend and extend through opening 340 and groove 219 of base 210.

Any means for attaching cap 310 to base 210 is within the scope of the invention. In one example, cap 310 includes a feature that snap-fits into base 210. In another example, the exterior of the base 330 has several circumferential ridges 350 shaped and located to engage internal threads 610 of base 210. In this particular example, the ridges are parallel and thus not external threads that would mate into the internal threads 610 of the base in a manner similar to that of the external threads of the locking ring. However, such a threaded cap is also within the scope of the invention.

Alternative Embodiments

Figure 11a shows a modified guide stem 240a, which includes a ball-shaped end 220c located within base 210. Modified guide stem 240a also has an axial opening 222a that is similar in function to axial opening 222 previously described. Modified guide stem 240a may be shorter than previously described guide stem 240 but otherwise functions similarly.

Figure 11b illustrates using alignment stem 1700 as described above. Locking ring 230 is used to secure the ball-shaped end 220c within base 210, thereby aligning axial opening 222a as desired. After removal of alignment stem 1700, a catheter is inserted directly into axial opening 222a so that it may be held in place by any convenient means for securing the catheter in place. For example, the diameter of axial opening 222a could be chosen so that, even though ball-shaped end 220c is constructed of a rigid material, friction alone would be adequate to grip the catheter in place yet allow sufficient movement to insert the catheter to the desired position. The catheter is tunneled under the skin as described above; the relatively shorter length of modified guide stem 240a permits the skin flap to cover the base without removal of a relatively longer guide stem 240, as previously described.

Figures 12a and 12b illustrate schematically still another example within the scope of the invention. Figure 12a shows alignment stem 1700 and a separate one-piece ball 220d located within base 210. Ball 220d is adapted to engage alignment stem 1700 according to the principles described above. Ball 220d has an axial opening 222b that is similar in function to axial opening 222 of the preferred embodiment. Base 210 also contains alignment material 290 as shown.

Alignment stem 1700 is employed as described above, and locking ring 230 is used to secure ball 220d within the base 210, thereby aligning axial opening 222b as desired. After removal of alignment stem 1700, catheter 229 is inserted directly into axial opening 222a, emerging from the distal outlet and then puncturing through alignment material 290, which secures catheter 229 in place. The catheter is then tunneled under the skin as described above for the preferred embodiment.

The catheters used in the preferred embodiment of neurosurgery typically range in size from 3 to 12 French (1 - 4 millimeters in diameter). This is small

enough that a wide range of materials are suitable for alignment material 290, notably many medical-grade silicones and urethanes.

Yet another variation on this embodiment combines two means for securing the catheter in place. For example, the first means could be either the
5 embodiment of Figures 11a and 11b, or the previously described embodiment of a two-piece ball 220 and relaxable stabilizer 227. The second means for securing catheter 229 in place could be the alignment material 290.

Reduced Profile Examples

10 Figures 13a - 13e are various views illustrating an alternate example of a two piece version of base 210. Two-piece base 1300 includes a mounting seat 1302 and a collar 1304. In this example, mounting seat 1302 includes a flange with bone screw holes. Mounting seat 1302 also includes a hemispherical recess for receiving a swiveling one or two piece ball-shaped movable member 220.
15 Movable member 220 includes an opening 223 into which a guide stem 240 is threaded. Cylindrical collar 1304 includes internal threads for receiving a locking member 230 for securing movable member 220, after it has been positioned to provide the desired trajectory, while an instrument 280 is inserted through guide stem 240 toward target 270. Collar 1304 includes a coupler, such
20 as legs that detachably snap-fit into receptacles 1308 in base 1302. After instrument 280 is guided to target 270, guide stem 240 is then removed over instrument 280. This allows relaxable stabilizer 227 to hold instrument 280 in place. Locking member 230 and collar 1304 are also then removed. Instrument 280 is bent laterally into a groove 1310 in base 1302. Cap 1312, which includes
25 legs 1314 for snap-fitting into receptacles 1308, is then snapped onto base 1302. Cap 1312 also includes one or more grooves 1316, which aligns with the one or more grooves 1310 in base 1302 for allowing instrument 280 to pass laterally therethrough. This example illustrates how, by separating base 210 into more than one piece (e.g., 1302 and 1304), its profile above the skull may
30 advantageously be reduced by removing one of the pieces (e.g., 1304).

Figures 14a-14b are various views illustrating another alternate example of a two piece version of base 210. Two-piece base 1400 includes a mounting seat 1402 and a collar 1404. In this example, mounting seat 1402 includes a flange with bone screw holes. Mounting seat 1402 also includes a hemispherical

recess for receiving a swiveling one or two piece ball-shaped movable member 220. Movable member 220 includes an opening 223 into which a guide stem 240 is threaded. Cylindrical collar 1404 includes internal threads for receiving a locking member 230 for securing movable member 220, after it has been
5 positioned to provide the desired trajectory, while an instrument 280 is inserted through guide stem 240 toward target 270. Collar 1404 includes a coupler, such as countersunk holes for receiving screws 1406 that detachably engage internally threaded receptacles 1408 in base 1402. This example illustrates how, by separating base 210 into more than one piece (e.g., 1402 and 1404), its profile
10 above the skull may advantageously be reduced by removing one of the pieces (e.g., 1404).

Figures 15a and 15b are various views illustrating another example of a low profile mounting seat 1502, to which a removable internally threaded collar can be snap-fit, along with a movable member 220 and guide stem 240. This
15 example includes three grooves 1504 into which an instrument 280 can be laterally bent. A matching cap with an aligning groove is then snap-fitted into the receptacles.

Figures 16a-16c are various views illustrating another example of a two-piece base 1600 including a mounting seat 1602, a removable internally-threaded
20 collar 1604, and a movable member 220. This example of mounting seat 1602 includes three grooves 1604 into which an instrument 280 can be laterally bent after removing collar 1604. In this example, collar 1604 includes a coupler, such as attachment feet 1606 that are pushed toward each other by the user in order to snap collar 1604 into and out of receptacles 1608 in mounting seat 1602. This
25 example also includes three grooves 1610 into which an instrument 280 can be laterally bent after removing collar 1604, as illustrated in Figure 17. A matching cap with an aligning groove is then snap-fitted into the receptacles 1608.

Figures 18a-18c are various views illustrating an alternate example of a low-profile mounting seat 1802 portion of a two-piece base and a cap 1804. In
30 this example, mounting seat 1802 includes three grooves 1806 into which an instrument 280 can be laterally bent. Cap 1804 includes a single groove 1808 that is aligned, by rotating cap 1804 with respect to mounting seat 1802 before snap-fitting it thereto, to the groove in mounting seat 1802 into which instrument 280 has been laterally bent. Three feet in cap 1804 align with matching

receptacles 1810 in mounting seat 1802 so that groove 1808 in cap 1804 is capable of being aligned with any of the grooves 1806 in mounting seat 1802.

Stabilizer Sliding Cap Example

5 Figures 19a-c are various views illustrating an alternative example capable of using a cap or other slide component to stabilize a catheter or other medical instrument. Figure 19a is a side view of a mounting seat 1902 with laterally extending flanges 1904 that include bone screw openings 1906. A hemispherical seat portion of mounting seat 1902 receives a one-piece ball 1908
10 with a trajectory passage 1910 extending therethrough. The hemispherical seat portion of mounting seat 1902 also includes an opening 1912 that aligns with passage 1910 as ball 1908 is swiveled within mounting seat 1902 by manipulating a guide stem that is threaded into passage 1910 as discussed above. In this example, a set screw locking member 1912 is inserted through an opening
15 1914 in mounting seat 1902 to secure ball 1908 in place after the desired position has been obtained. A hemispherically conformal cap 1916 is situated about the top of ball 1908. Figure 19b is a top view illustrating opening 1918 being concentrically aligned to the top opening of passage 1910 through ball 1908. Cap 1916 also includes a slot 1920 through which set screw 1922 passes.
20 Set screw 1922 engages an underlying threaded opening on the top surface of ball 1908. Figure 19c is a top view illustrating how cap 1916 can be slid along ball 1908 in the direction of slot 1920 to offset opening 1918 in cap 1916 from the top opening of passage 1910 in ball 1908. This reduces the effective area of passage 1910 through which a catheter or other instrument has been passed. By
25 tightening set screw 1922, cap 1916 is used to grasp and stabilize the catheter or other instrument through passage 1910. Cap 1916 is any rigid, semi-rigid, relaxable, or flexible material (or combination thereof) suitable for grasping and stabilizing an instrument by narrowing the effective cross-sectional area of passage 1910, e.g., by offsetting the opening 1918 of cap 1916.

30

Other Aspects

The invention as described above can be used with various known aspects of remote actuation systems, perhaps with minor modifications to accommodate the features of the invention that would be within the ordinary

skill of the art. Suitable examples are the mechanical and hydraulic remote actuation and control devices taught in the International Patent Application cited above. Similarly, mechanisms to laterally displace the apparatus without changing the trajectory of the catheter or instrument held by the relaxable stabilizer in the movable member may be employed. An example would be the stage mechanism taught in the same International Patent Application. Any suitable system for computerized monitoring and/or control of the invention may be employed.

10 **Other Uses**

The invention can be practiced in conjunction with trajectory guides adapted for various parts of the body, including uses related to biopsies or therapy provided to organs in or near the abdomen or pelvis. Among the uses are liver biopsies, renal biopsies, pancreatic biopsies, adrenal biopsies. In addition, some procedures require both a biopsy as well as a therapy. The biopsy needle is used first and then an instrument used in therapy is substituted for the biopsy needle. The instrument for applying therapy includes instruments for thermal ablation, and instruments for providing shunts to various organs such as TIPS (transjugular interhepatic portal systemic shunts). The inventive trajectory guide can also be used to conduct biliary drainages, and used to conduct other biopsies and treatments at or near the abdomen of the pelvis. The trajectory guide can also be used for procedures on the back and near the spine of a patient. Nerve blocks, epidural injections, facet injections, sacroiliac joint injections, and spinal cordotomy are just a few of the procedures possible with the trajectory guide. Non-brain treatments and biopsies in the head and neck can also be accomplished using the trajectory guide. Trigeminal neuralgia can be treated using the trajectory guide. Biopsies of the pleura, the lung, and the mediastinum and removal of emphysematous to reduce the volume of the lung can be done percutaneously using the trajectory guide. The trajectory guide can also be used for fetal surgery such as for diversion of fetal hydrocephalus, and for treatment of fetal hydronephrosis. These are just a sampling of the possible procedures that can be done using the body portal type trajectory guide. Numerous other procedures will be accomplished using this device. In addition, the device will give rise to other future surgical procedures.

It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments may be used in combination with each other. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The

5 scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms “including” and “in which” are used as the plain-English equivalents of the respective terms “including” and “wherein.”